R E M A R K S

Applicants' present claims are directed to an ophthalmic solution comprising latanoprost as an active ingredient, wherein latanoprost is stabilized to be stored at room temperature by at least one means selected from the following 1) and 2):

1) adjusting the pH of the solution to 5.0 to 6.25 and

2) adding ε-aminocaproic acid to the solution.

In discovering applicants' present claims, the present inventors first focused attention on the physical properties of latanoprost in order to solve the problem that the commercially available latanoprost ophthalmic solution lacks stability. The present inventors conducted various studies and finally discovered a latanoprost ophthalmic solution that can be stored at room temperature. Specifically, the present inventors discovered that their latanoprost ophthalmic solution can be stored at room temperature by adjusting the pH of the solution to 5.0 to 6.25 or by adding ε-aminocaproic acid to the solution. That is, applicants' present claims possess a newly achieved advantageous effect that a latanoprost ophthalmic solution can be stored at room temperature by improving the stability of

latanoprost, which has been a problem that has not been able to be solved for many years.

Claims 1 and 2 were rejected under 35 USC 102 as being anticipated by USP 6,011,062 to Schneider et al. for the reasons set forth in item nos. 2 and 3 on page 2 of the Office Action.

The Office Action refers to EXAMPLE 2 of Schneider et al. However, the formulations described in EXAMPLE 2 contain Compound 32 or 33 (Compounds 32 and 33 are defined in column 6 of Schneider et al.), which do not include latanoprost. Since Compounds 32 and 33 are distinctly different from latanoprost, it is respectfully submitted that the novelty of applicants' present claims is not precluded by the description in EXAMPLE 2 of Schneider et al.

Moreover, it is stated on page 2 of the Office Action that "Schneider teaches that latanoprost can be used in that invention in column 5, line 57." However, latanoprost is only one of 34 listed compounds (prostaglandin derivatives) in column 4 to 6 of Schneider et al.

Anticipation is not made out by a hindsight selection based on applicants' disclosure in view of many variables of a broad

disclosure, such as in Schneider et al. In re Rushig, 145 USPQ 274, 282 (CCPA 1965).

It is therefore respectfully submitted that novelty of applicants' present claims is not precluded from Schneider et al., wherein latanoprost is merely disclosed as one example of 34 prostaglandin derivatives and no experiment or study was conducted with respect to latanoprost.

In view of the above, withdrawal of the anticipation rejection is respectfully requested.

Claims 3 and 4 were rejected under 35 USC 103 as being unpatentable over USP 6,011,062 to Schneider et al. in view of USP 5,916,550 to Inada et al. for the reasons indicated in item nos. 5 and 6 on page 3 of the Office Action.

It was admitted in the Office Action that Schneider et al. do not teach epsilon-aminocaproic acid.

As discussed above, applicants' present claims are characterized in that latanoprost is stabilized by adjusting the pH to 5.0 to 6.25 or by adding ε-aminocaproic acid.

Inada et al. do not describe the stability of latanoprost, let alone describe latanoprost itself.

However, Schneider et al. and Inada et al. do not teach or suggest the stabilization effect on latanoprost by a pH adjustment or the addition of ε-aminocaproic acid that are the characteristic features of applicants' present claims.

Accordingly, both Schneider et al. and Inada et al. do not disclose the stability of the latanoprost and do not describe the advantageous results of applicants' present claims, which are demonstrated in Tables 1 and 3 on pages 10 and 16, respectively, of the present specification, and which are reproduced hereinbelow.

Table 1

Stability of latanoprost (Residual ratio (%) after storage for 28 days)

		according to applicants' present claims						
	pH 4.0	pH 5.0	pH 5.5	pH 6.0	pH 6.25	pH 6.5	pH 6.7	pH 8.0
60	87.4	98.9	98.0	98.9	95.0	92.4	93.4	30.0*
70	76.7	94.9	94.6	93.1	92.0	82.7	78.1	14.1**

*Value on 21st day, ** value on 12th day

Table 3

	Additives	Storage at 50 for eight weeks	Storage at 80 for four weeks
Formulation 1	Crystalline sodium dihydrogenphosphate	88.7%	24.0%
Formulation 2	PEG 400	88.8%	25.9%
Formulation 3	Propylene glycol	88.1%	26.1%
Formulation 4	Trehalose	83.7%	26.4%
Formulation 5	Isopropanol	88.9%	28.9%
Formulation 6	α-Cyclodextrin	86.6%	22.1%
Formulation 7	Citric acid	87.1%	6.3%
Formulation 8	ε-Aminocaproic acid according to applicants' present claims	93.1%	51.8%

It is respectfully submitted that one of ordinary skill in the art would not arrive at applicants' present claims from the disclosures of Schneider et al. and Inada et al.

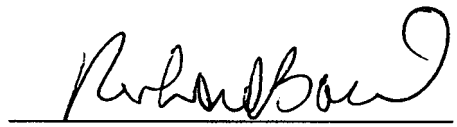
Withdrawal of the 35 USC 103 rejection is thus respectfully requested.

Reconsideration is requested. Allowance is solicited.

An INFORMATION DISCLOSURE STATEMENT and a STATEMENT UNDER 37 CFR 1.78(f) (EFFECTIVE NOVEMBER 1, 2007) are being filed concomitantly herewith.

If the Examiner has any comments, questions, objections or recommendations, the Examiner is invited to telephone the undersigned at the telephone number given below for prompt action.

Respectfully submitted,



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Encs.: (1) INFORMATION DISCLOSURE STATEMENT
(2) STATEMENT UNDER 37 CFR 1.78(f)
(EFFECTIVE NOVEMBER 1, 2007)